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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,990	03/27/2001	D. Wade Walke	LEX-0152-USA	9270

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LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/27/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/818,990

Applicant(s)

WALKE ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 1, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's response, on April 1, 2003, Paper No. 19, to the first Office Action on the Merits of this case is acknowledged. It is acknowledged that applicants have amended Claims 1 and 2. Claims 1-3 and 6-10 are hereby reconsidered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Rejection of Claims 1-3 and 6-10 under 35 U.S.C. 101 is maintained. Claims 1-3 and 6-10 were rejected under 35 U.S.C. 101 because the claimed invention is not supported by a well established utility for either the nucleic acid molecule of SEQ ID NO: 1 or any nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2. Furthermore, the claimed invention is not supported by an asserted utility based on either a demonstrated function for the protein of SEQ ID NO: 2 or by a deduced function for said protein supported by homology to known proteins. The reasons for rejection are further described in the prior action.

Applicants argue that the recited invention has a number of substantial and credible utilities including diagnostic assays, forensic analysis, DNA chip technology, identification of the coding sequence, and chromosomal mapping. Applicants also state that the prior action argues that use of the present sequences in forensic analysis is not a specific utility because the utility is "only potential and not in currently available practical form". Applicants also present data showing that, a sequence sharing nearly 100% identity at the protein level over the entire length of the claimed sequence is present in GenBank and has been annotated as human myopalladin, that myopalladin has been shown to be involved in muscle structure and, that "...there

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can be no question that those skilled in the art would clearly believe that Applicants' sequence is a muscle protein."

These arguments are not found to be persuasive. For example, use of the present sequences in forensic analysis is not a specific utility because the presence of polymorphisms in human DNA is well established and virtually any locus on a human chromosome will exhibit one or more polymorphisms which could be so used not because the use of the present sequences is "only potential and not in currently available practical form". Applicants have not identified any particular reason for use of this particular sequence in forensic analysis or any particular benefit that would derive from analysis of a polymorphism in said sequence. Applicants have also not identified any particular reason for use of this particular polynucleotide in "DNA chips" for the discovery of drugs associated with human disease and no specific human diseases have been shown to be associated with or correlated with alterations in this particular polynucleotide. Likewise, applicants have not identified any particular reason for identifying the coding sequence or using this polynucleotide in mapping chromosome 10. Based on the alignment of the protein encoded by SEQ ID NO: 1 with GenBank Acc# AF328296 and the report of Bang et al, 2001, the identity of said protein as myopalladin is credible. However, this argument constitutes only hindsight reasoning. The specification fails to assert myopalladin activity for the recited sequences. On page 2, lines 1-5, the disclosure states "The novel human proteins (NHPs) described for the first time herein share structural similarity with, *inter alia*, mammalian muscle proteins (myosin light chain kinase, telokin, IgG like C2 domains, myotilin), and modifiers and anchors of thereof". Such an assertion of structural similarity does not constitute an assertion of function. Furthermore, applicant's assertion that, based on homology to myopalladin, "there can

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be no question that those skilled in the art would clearly believe that Applicants' sequence is a muscle protein" also lacks any assertion of function. Based on these arguments and those found in the prior action, rejection of Claims 1-3 and 6-10 under 35 U.S.C. 101 is maintained.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 6-10 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of nucleic acid molecules with SEQ ID NO:1 or derivatives thereof.

The specification does not contain any disclosure of the function of said nucleic acid sequences. The genus of polynucleotides that comprise these above nucleic acid molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses no species of the claimed genus which, is insufficient to put one of skill in the art in possession of the attributes and features of

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all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan L. Swope, Ph.D.


REBECCA E. PROUTY
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